IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA ex rel. NHCA-TEV, LLC, and on behalf of STATE OF CALIFORNIA, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF FLORIDA, STATE OF GEORGIA, STATE OF HAWAII, STATE OF ILLINOIS, CITY OF CHICAGO, STATE OF INDIANA, STATE OF LOUISIANA, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF MONTANA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF NEW YORK, STATE OF NORTH CAROLINA, STATE OF OKLAHOMA, STATE OF RHODE ISLAND, STATE OF TENNESSEE, STATE OF TEXAS, COMMONWEALTH OF VIRGINIA, and STATE OF WISCONSIN, **Plaintiff,** **v.** **TEVA PHARMACEUTICAL PRODUCTS LTD.,** **TEVA PHARMACEUTICALS USA, INC.,** **TEVA NEUROSCIENCE, INC., and** **TEVA SALES AND MARKETING, INC.,** **Defendants.**	**CIVIL ACTION** **NO. 17-2040**

M E M O R A N D U M

DuBois, J. **November 25, 2019**

I. INTRODUCTION

This is a *qui tam* action brought against Teva Pharmaceutical Products Ltd., Teva Pharmaceuticals USA, Inc., Teva Neuroscience, Inc., and Teva Sales and Marketing, Inc.

(collectively "Teva"). Relator, NHCA-TEV, LLC, alleges that Teva provided unlawful kickbacks to medical providers to encourage them to prescribe Copaxone, a multiple sclerosis medication manufactured by Teva, in violation of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b *et seq*. Relator brings these claims on behalf of the United States pursuant to the False Claims Act ("FCA"), 31 U.S.C. §§ 3729–3733 and on behalf of various states, the District of Columbia, and one municipality under their respective state and local false claims statutes.

Two motions are presently pending before the Court: (1) the United States' Motion to Dismiss Relator's First Amended Complaint (Document No. 30, filed December 17, 2018), and (2) Defendants' Motion to Dismiss Relator's First Amended Complaint (Document No. 27, filed November 21, 2018). For the reasons that follow, the Court grants the United States' Motion to Dismiss Relator's First Amended Complaint and denies as moot Defendants' Motion to Dismiss Relator's First Amended Complaint.

II. BACKGROUND

Relator NHCA-TEV claims that Teva engaged in two unlawful schemes involving "'in kind' remuneration" to prescribers of Copaxone. First Am. Compl. ¶ 81. These alleged schemes involved Teva providing free (1) reimbursement support services to help patients secure insurance coverage for Copaxone and (2) nursing services to assist patients in administering Copaxone after it was prescribed. *Id.* ¶¶ 1, 81–82. According to relator, these services saved healthcare providers time and money and therefore constitute illegal kickbacks in violation of the AKS. *Id.* ¶¶ 96–100. Relator contends that these illegal kickbacks resulted in the filing of false claims for payment to the United States, in violation of the FCA. *Id.* ¶ 34.

Relator is a limited liability company established by the National Health Care Analysis Group ("NHCA Group"), and is one of several NHCA Group-affiliates that have brought *qui tam*

actions against healthcare companies under the FCA and analogous state and local false claims statutes. Relator Opp. 2. As of November 2019, twelve of these *qui tam* actions have been filed, each asserting allegations similar to those in NHCA-TEV's First Amended Complaint.[1] Gov't Reply 1 n.1; Hr'g Tr. 21:24–22:14.

After investigating relator's allegations in this case, the Government notified the Court that it declined to intervene on June 5, 2018 (Document No. 8).[2] Thereafter, relator continued to pursue the action on behalf of the Government. Both Teva and the Government then each filed motions to dismiss (Document Nos. 27 and 30, filed November 21, 2018 and December 17, 2018, respectively).[3] The motions are fully briefed and ripe for decision.

III. LEGAL STANDARD

The FCA permits private individuals to bring a *qui tam* action as relators on behalf of the United States against anyone who submits "false or fraudulent" claims to the Government for payment. 31 U.S.C. §§ 3729(a)(1)(A), 3730(b)(1). Although the relator initiates the lawsuit, the Government may elect to intervene in the action and take "primary responsibility for prosecuting the action." *Id.* §§ 3730(b)(2)-(3), (c)(1). Alternatively, the Government may decline to

[1] *See United States ex rel. SAPF, LLC, et al. v. Amgen, Inc., et al.*, No. 16-cv-5203 (E.D. Pa.); *United States ex rel. SMSPF, LLC, et al. v. EMD Serono, Inc., et al.*, No. 16-5594 (E.D. Pa.); *United States ex rel. SMSF, LLC, et al. v. Biogen Inc., et al.*, No. 1:16-cv-11379 (D. Mass.); *United States ex rel. SCEF, LLC v. Astra Zeneca PLC, et al.*, No. 17-cv-1328 (W.D. Wash.); *United States ex rel. Miller, et al. v. AbbVie, Inc.*, No. 3:16-cv-2111 (N.D. Tex.); *United States ex rel. Carle, et al. v. Otsuka Holdings Co., et al.*, No. 17-cv-966 (N.D. Ill.); *United States ex rel. CIMZNHCA v. UCB, Inc., et al.*, No. 3:17-cv-00765 (S.D. Ill.); *United States ex rel. Health Choice Group, LLC. v. Bayer Corp., et al.*, No. 5:17-cv-126 (E.D. Tex.); *United States ex rel. Health Choice All., LLC v. Eli Lilly & Co., et al.*, No. 5:17-cv-123 (E.D. Tex.); *United States ex rel. Health Choice Advocates, LLC v. Gilead, et al.*, No. 5:17-cv-121 (E.D. Tex.); *United States ex rel. Doe and APBQR, LLC v. Sanofi-Aventis U.S. LLC, et al.*, No. 16-5107 (S.D.N.Y.).

[2] On June 19, 2018, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Wisconsin, and the District of Columbia filed a Notice of Election to Decline Intervention (Document No. 12).

[3] A representative of the National Association of Medicaid Fraud Control Units has represented that all named state plaintiffs consent to the Government's motion to dismiss "so long as it is without prejudice to the states," except for the state of New Jersey, which has not taken a position on the motion. Gov't Mot. Dismiss 1 n.1.

intervene, in which case the relator may proceed to litigate on behalf of the United States. *Id.* §§ 3730(b)(4)(B), (c)(3).

However, because a relator brings its action in the name of the United States, the Government's decision to decline to intervene does not completely deny the Government control over the litigation. *See United States v. EMD Serono, Inc.*, 370 F. Supp. 3d 483, 487 (E.D. Pa. 2019); *United States ex rel. CIMZNHCA, LLC v. UCB, Inc.*, No. 17-CV-765-SMY-MAB, 2019 WL 1598109, at *2 (S.D. Ill. Apr. 15, 2019). Importantly, the FCA permits the Government to "dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion." 31 U.S.C. § 3730(c)(2)(A). The Government preserves this right to dismiss the *qui tam* action, regardless of whether it intervenes or not. *See Kellogg Brown & Root Servs., Inc. v. United States ex rel. Carter*, 135 S. Ct. 1970, 1973–74 (2015).

Although the FCA establishes the Government's right to dismiss a *qui tam* action, it does not expressly provide a standard of review for courts to apply when considering motions to dismiss filed by the Government. Circuit courts have articulated two standards for dismissal of *qui tam* actions by the Government under § 3730(c)(2)(A) over a relator's objection: a "rational relation" test and an "unfettered right" standard.

The rational relation test, which has been adopted by the Ninth and Tenth Circuits, consists of a two-part inquiry. To dismiss the relator's suit, the Government must (1) identify a "valid governmental purpose" and (2) demonstrate that a "rational relation" exists between dismissal and accomplishment of the Government's stated purpose. *United States ex rel., Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139, 1145 (9th Cir. 1998);

Ridenour v. Kaiser-Hill Co., 397 F.3d 925, 936 (10th Cir. 2005). If the Government satisfies these first two requirements, the burden shifts to the relator to show that "dismissal is fraudulent, arbitrary and capricious, or illegal." *Sequoia Orange*, 151 F.3d at 1145; *Ridenour*, 397 F.3d at 936.

In contrast, the D.C. Circuit has interpreted the FCA to give the Government an "unfettered right" to dismiss *qui tam* actions brought on the Government's behalf. *Swift v. United States*, 318 F.3d 250, 252 (D.C. Cir. 2003); *see also Hoyte v. Am. Nat'l Red Cross*, 517 F.3d 61 (D.C. Cir. 2008). Under this standard, the executive branch has "absolute discretion" over "whether to bring an action on behalf of the United States," effectively rendering the Government's decision to dismiss "unreviewable." *Swift*, 318 F.3d at 253.

The Third Circuit has not determined the proper standard for dismissal of a relator's FCA action over the relator's objections. *See Chang v. Children's Advocacy Ctr. of Delaware Weih Steve Chang*, 938 F.3d 384, 387 (3d Cir. 2019) (declining to "take a side in this circuit split" because dismissal was warranted under both tests).

Although the rational relation test is "slightly more demanding" than the unfettered right standard, both standards are extremely deferential to the Government. *Polansky v. Executive Health Resources, Inc.*, No. 12-CV-4239, 2019 WL 5790061, at *8 (E.D. Pa. Nov. 5, 2019); *see also United States ex rel. Surdovel v. Digirad Imaging Sols.*, No. CIV.A. 07-0458, 2013 WL 6178987, at *2 (E.D. Pa. Nov. 25, 2013). Noting the significant amount of deference that both standards give the Government, the Court concludes that both standards have been met in this case. For this reason, the Court, like the Third Circuit in *Chang*, declines to decide which is the proper standard of review and, instead, applies the rational relation test because it is the "more restrictive standard." *Chang*, 938 F.3d at 387; *see also Polansky*, 2019 WL 5790061, at *8. *But*

see EMD Serono, Inc. 370 F. Supp. 3d at 488–89 (adopting the rational relation standard because it "accords with statutory interpretation and fosters transparency"). The Court next turns to an analysis of the rational relation test as applied in this case.

IV. DISCUSSION

A. Valid Governmental Purposes

For a court to dismiss an FCA case over a relator's objections under the rational relation test, the Government must first show that there is a "valid government purpose" for dismissal. *Sequoia Orange*, 151 F.3d at 1145; *Ridenour*, 397 F.3d at 935. In this case, the Government identifies two purposes for dismissal of relator's FCA claims: (1) "preserving scarce government resources"; and (2) "protecting important policy prerogatives of the federal government's healthcare programs." Gov't Mot. Dismiss 14.

Courts have recognized both of these putative purposes as valid and legitimate in the context of dismissal under § 3730(c)(2)(A). First, the *Sequoia Orange* court held that the "government can legitimately consider the burden imposed on the taxpayers by its litigation, and that, even if the relators were to litigate the FCA claims, the government would continue to incur enormous internal staff costs." 151 F.3d at 1146; *see also Chang*, 938 F.3d at 388. The Government's interest in avoiding potentially burdensome or unnecessary litigation costs is legitimate even when a relator's claims appear meritorious. *See, e.g.*, *Sequoia Orange*, 151 F.3d at 1145–46; *Ridenour*, 397 F.3d at 939–40.

Second, courts have similarly accepted the Government's putative policy interests in patient care and enforcement prerogatives as valid government purposes. *See, e.g.*, *EMD Serono*, 370 F. Supp. 3d at 489; *United States, ex rel. SCEF, LLC v. Astrazeneca, Inc.*, No. 2:17-CV-1328-RSL, 2019 WL 5725182, at *2–3 (W.D. Wash. Nov. 5, 2019). In this case, the

Government argues that "federal healthcare programs have a strong interest in ensuring that . . . patients have access to basic product support relating to their medication," including educational resources such as a toll-free assistance phone line and instructions about how to administer or store the medicine. Gov't Mot. Dismiss 15–16. Both of these interests satisfy the first prong of the *Sequoia Orange* test.

B. Rational Relation Between Dismissal and the Government's Stated Purposes

Second, there must exist a "rational relation" between the government's valid purpose and dismissal of the relator's FCA claims. This is not a rigorous test. *Ridenour*, 397 F.3d at 936 (noting that a rational relation need not be a "tight fitting relationship"). "It is enough if there are 'plausible, or arguable reasons supporting the agency decision.'" *EMD Serono*, 370 F. Supp. 3d at 488 (quoting *Ridenour*, 397 F.3d at 937).

In this case, a rational relation exists between dismissal and the Government's stated purpose of managing litigation costs. The Government states that relator's allegations implicate over 1.5 million prescriptions, more than 23,000 physicians, and tens of thousands of Medicare, Medicaid, and Tricare beneficiaries over a period of at least six years. Gov't Mot. Dismiss 14–15; Hr'g Tr. 14:1–18. The broad scope of these allegations, the Government argues, would impose a significant burden monitoring the litigation and responding to discovery requests.[4] *Id.* These future costs would be in addition to the 1,500 hours that the Government claims it has already spent investigating and monitoring all of the NHCA-related actions. Gov't Mot. Dismiss 14 n.6. In response, relator argues that dismissal is premature because the Government has not sufficiently investigated relator's claims to make such an appraisal. Relator Opp. 9.

[4] The Government states that these burdens would include the cost of reviewing and producing documents from various federal healthcare programs, analyzing patient health information, and preparing witnesses for depositions. Gov't Mot. Dismiss 15.

While courts generally require that the Government conduct some investigation into a relator's claims, "the FCA does not require the government to 'fully investigate' an alleged FCA violation before moving to dismiss." *United States ex rel. Toomer v. TerraPower, LLC*, No. 4:16-cv-00226-DCN, 2018 WL 4934070, at *6 (D. Idaho Oct. 10, 2018). In this case, the Government claims it interviewed a high-level relator executive, examined the information provided by relator, interviewed physicians who prescribed Copaxone, assessed prescriber data, and conferred with experts at the Department of Health and Human Services Office of Inspector General, which oversees Government enforcement of the AKS. Hr'g Tr. 15:17–16:2. After conducting this investigation, the Government concluded that it was unlikely that relator's claims would be successful, and that even if they were, "any outcome in this case would not exceed the burden that this case would impose on the Government's resources." *Id.* 16:5–8. Any more formal cost-benefit analysis is unnecessary in order to demonstrate a rational relation between dismissal and the purpose of conserving Government resources. *See, e.g.*, *United States ex rel. Borzilleri v. AbbVie, Inc.*, No. 15-CV-7881 (JMF), 2019 WL 3203000, at *2 (S.D.N.Y. July 16, 2019) (concluding that "the Government's determination that it would prefer to avoid these [litigation] costs and expend its finite resources elsewhere is . . . a 'valid government purpose' rationally related to dismissal of the case"). Courts in four of the other NHCA-related *qui tam* actions have agreed, concluding that the Government's investigation into the relators' claims was "extensive." *See Health Choice All. LLC ex rel. United States v. Eli Lilly & Co., Inc.*, No. 517CV00123RWSCMC, 2019 WL 4727422, at *7 (E.D. Tex. Sept. 27, 2019) (dismissing two NHCA-related cases filed in the Eastern District of Texas); *SCEF, LLC*, 2019 WL 5725182, at

*3; *EMD Serono*, 370 F. Supp. 3d at 490.[5] This Court agrees with these four cases and concludes that the Government's investigation was sufficient to satisfy the "rational relation" requirement of the *Sequoia Orange* test.

A rational relation also exists between the Government's stated policy interests and dismissal of this case. The Government notes that Copaxone is an expensive medication—costing approximately $80,000 per year—and challenging to administer because it is an injectable biologic. Hr'g Tr. 18:1–11. Accordingly, the Government takes the position that Teva's reimbursement support services and nursing services are "common industry practices [that are] . . . appropriate and beneficial to federal healthcare programs and their beneficiaries." Gov't Mot. Dismiss 16. In response, relator argues generally that "there is no public policy rationale for the kickback schemes alleged" and that the alleged schemes create perverse incentives that "undermine the independence of physician and patient decision-making, and raise healthcare costs." Relator Opp. 12 (internal quotation marks omitted). The Court rejects this argument because it fails to undercut the Government's position that these services are common and beneficial to patient care. The Court thus finds that the Government's policy interests plausibly support its decision to dismiss this case.

C. Relator's Burden to Show Fraudulent, Arbitrary and Capricious, or Illegal Dismissal

The Court having determined that the Government identified a valid purpose rationally related to dismissal, the burden shifts to the relator to show that dismissal would be "fraudulent, arbitrary and capricious, or illegal." *Sequoia Orange*, 151 F.3d at 1145.

[5] *But see CIMZNHCA*, 2019 WL 1598109, at *3 (denying the Government's motion to dismiss on the ground that, *inter alia*, "it did not assess or analyze the costs it would likely incur versus the potential recovery that would flow to the Government if this case were to proceed").

Relator fails to make this showing. Relator contends that it would be arbitrary to dismiss its claims at such an early phase of the litigation because "it is unknown what burden, if any, the United States will face" because the Government's other litigation burdens may change. Relator Opp. 9. However, several district courts have rejected the argument that failure to more fully investigate relator's claim is "arbitrary and capricious." *See, e.g.*, *EMD Serono*, 370 F. Supp. 3d at 489–90; *Health Choice All. LLC*, 2019 WL 4727422, at *7 (rejecting as speculation relator's argument that the Government misrepresented the depth of its investigation); *United States ex rel. Nicholson v. Spigelman*, No. 10 C 3361, 2011 WL 2683161, at *3 (N.D. Ill. July 8, 2011) ("The government's cost-benefit calculation may be sound or it may be short-sighted, but it cannot be deemed arbitrary and capricious."). Based on this authority, the Court concludes that relator in this case has failed to meet its burden to show that dismissal would be fraudulent, arbitrary and capricious, or illegal.

D. Dismissal of Claims

The Government has met its burden of establishing grounds for dismissal of the FCA claims in this *qui tam* action under the rational relation test for all of the foregoing reasons. Thus, all such claims are dismissed with prejudice as to relator. The FCA claims are dismissed without prejudice as to the Government because the Government has not asserted any claims, "or even acquiesced to [relator] pursuing the FCA claims on [its] own." *Toomer*, 2018 WL 4934070, at *7 (granting the Government's motion to dismiss an FCA action with prejudice as to the relator and without prejudice as to the Government); *see also United States ex rel. Wickliffe v. EMC Corp.*, No. 1-06-CV-64-DAK, 2010 WL 3662467, at *2 (D. Utah Sep. 15, 2010) (same). For this reason, the Government may bring these or similar claims against Teva in the future if it decides to do so.

Dismissal of relator's FCA claims leaves only relator's state and local law claims in this action. In its First Amended Complaint, relator asserts that the Court has jurisdiction over these state and local claims based on 31 U.S.C. § 3732(b), which provides that "district courts shall have jurisdiction over any action brought under the laws of any State for the recovery of funds paid by a State or local government if the action arises from the same transaction or occurrence as an action brought under [the FCA]." First Am. Comp. ¶ 8. Because the FCA claims asserted in the First Amended Complaint have been dismissed, § 3732(b) is no longer applicable. That leaves supplemental jurisdiction under 28 U.S.C. § 1367 as the only potential basis of federal jurisdiction in this case. Section 1367 provides, *inter alia*, that a district court "may decline to exercise supplemental jurisdiction over a claim [if] . . . the district court has dismissed all claims over which it has original jurisdiction." 28 U.S.C. § 1367(c)(3). In such cases, "where the claim over which the district court has original jurisdiction is dismissed before trial," the Third Circuit has held that "the district court *must* decline to decide the pendent state law claims unless considerations of judicial economy, convenience, and fairness to the parties provide an affirmative justification for doing so." *Hedges v. Musco*, 204 F.3d 109, 123 (3d Cir. 2000) (quoting *Borough of West Mifflin v. Lancaster*, 45 F.3d 780, 788 (3d Cir. 1995)).

No affirmative justification for exercising supplemental jurisdiction over the remaining state and local claims exists in this case. The Court reaches this conclusion because the FCA claims have been dismissed at an early stage of litigation and exercising supplemental jurisdiction would require the Court to apply the statutes of 27 jurisdictions in one case. *See, e.g.*, *Borzilleri*, 2019 WL 3203000, at *3; *United States v. Medco Health Sols., Inc.*, No. CV 11-684-RGA, 2017 WL 63006, at *13 (D. Del. Jan. 5, 2017); *United States v. Medco Health Sys., Inc.*, No. CIV. 12-522 NLH AMD, 2013 WL 6858758, at *9 (D.N.J. Dec. 30, 2013). The Court

thus declines to exercise supplemental jurisdiction over relator's state and local claims and dismisses these claims without prejudice.

V. CONCLUSION

For the foregoing reasons, the United States' Motion to Dismiss Relator's First Amended Complaint is granted. The Court dismisses relator's claims under the FCA with prejudice as to relator and without prejudice as to the Government. The Court dismisses relator's state and local law claims without prejudice. As a result, Defendants' Motion to Dismiss Relator's First Amended Complaint is denied as moot. An appropriate order follows.